

Amendments to the Claims

This listing of claims will replace all prior listings of claims in the application.

Listing of Claims

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1. (Cancelled).
2. (Cancelled).
3. (Cancelled).
4. (Cancelled).
5. (Cancelled).
6. (Cancelled).
7. (Cancelled).
8. (Cancelled).
9. (Cancelled).
10. (Cancelled).
11. (Cancelled).
12. (Cancelled).
13. (Cancelled).
14. (Cancelled).
15. (Cancelled).
16. (Cancelled).
17. (Cancelled).
18. (Cancelled).
19. (Cancelled).
20. (Cancelled).
21. (Cancelled).
22. (Cancelled).
23. (Cancelled).
24. (Cancelled).
25. (Cancelled).
26. (Cancelled).
27. (Cancelled).
28. (Cancelled).
29. (Cancelled).
30. (Cancelled).

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31. (Cancelled).

32. (New) A screening device for use with an immunoassay test membrane to which a specimen is applied for testing for the presence of a compound in the specimen, the test membrane having at least one test zone that changes reflectivity as a function of the concentration of the compound in the specimen, at least one control zone that changes reflectivity upon the application of the specimen and a background zone, said screening device including:

*the housing*

*the window*

a receiving bracket for removably receiving the test membrane;

a light source directed to said receiving bracket for illuminating the test membrane;

a photosensitive detector assembly directed to said receiving bracket for receiving light reflected by the test membrane, said photosensitive detector generating output signals representative of the concentrations of light reflected by the zones on the test membrane;

a processor connected to said photosensitive detector assembly to receive the photosensitive detector assembly output signals and configured to, based on the output signals:

compare the concentration of light reflected from the control zone to a first reference value to determine if the test is successful;

compare the concentration of light reflected from the test zone to a second reference value; and

if the test is successful, generate data representative of the presence of the compound in the specimen based on the comparison of the concentration of light reflected from the test zone to the second reference value.

33. (New) The screening device of Claim 32, wherein:

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the test membrane background zone reflects a fixed amount of light;

said photosensitive detector assembly generates output signals representative of the concentrations of light reflected by the test zone, the control zone and the background zone of the test membrane; and

said processor receives the output signals from said photosensitive detector assembly and is further configured to determine the first reference value based on the concentration of light reflected from the background zone.

34. (New) The screening device of Claim 32, wherein:  
the test membrane background zone reflects a fixed amount of light;

said photosensitive detector assembly generates output signals representative of the concentrations of light reflected by the test zone, the control zone and the background zone of the test membrane; and

C4 said processor receives the output signals from said photosensitive detector assembly and is further configured to determine the second reference value based on the concentration of light reflected from the test membrane background zone.

35. (New) The screening device of Claim 32, wherein said processor is further configured to determine the second reference value based on the concentration of light reflected from the test membrane control zone.

36. (New) The screening device of Claim 32, wherein:  
the light reflected by the test zone and the control zone of the test membrane is visible light; and

said photosensitive detector assembly is configured to detect the concentrations of visible light reflection by the test zone and the control zone of the test membrane.

37. (New) The screening device of Claim 32, wherein said processor is configured to, if the test is successful, based on the comparison of the concentration of light reflected from the test zone to the second reference value, generate data representative of a qualitative analysis of the presence of the compound in the specimen.

38. (New) The screening device of Claim 31, wherein said processor is configured to, if the test is successful, based on the comparison of the concentration of light reflected from the test zone to the second reference value, generate data representative of a quantitative analysis of the presence of the compound in the specimen.

C4 39. (New) The screening device of Claim 32, wherein: a display is attached to said processor; and said processor is connected to said display and is configured to control actuation of said display so that: if the test is not successful, said processor causes said display to generate a message indicating the test is not successful; and, if the test is successful, said processor causes said display to generate a message indicating the presence/absence of the compound in the specimen.

40. (New) The screening device of Claim 32, wherein: said photosensitive detector assembly generates output signals representative of concentration of light reflected from the test membrane across the test zone, the control zone and background zones that border the test zone and the control zone; and

said processor is further configured to: based on the output signals representative of the concentration of light reflected by the test zone and background zones on opposed sides of the test zone, determine the concentrations of light reflected by the test zone; and, based on the output signals representative of the concentrations of light reflected by the control zone and background zones on opposed sides of the control zone, determine the concentration of light reflected by the control zone.

41. (New) The screening device of Claim 32, wherein said processor is further configured to:

based on the output signals from said photosensitive detector assembly, determine the position of the control zone on the test membrane;

based on the determination of the position of the control zone, determine the position of the test zone on the test membrane; and

C4 based on the position of the test zone on the test membrane and the output signals from said photosensitive detector assembly, determine the concentration of light reflected from the test zone.

42. (New) A method of performing a screening test for the presence of a compound in a specimen of body fluid, said method including the steps of:

flowing the specimen over a membrane that is contained within a cartridge, the cartridge having a window through which a portion of the membrane is exposed, the exposed portion of the membrane having at least one test zone that changes reflectivity as a function of the concentration of the compound in the specimen, at least one control zone that changes reflectivity upon the application of the specimen and a background zone;

attaching the cartridge to a screening device;  
directing a light to the exposed portion of the membrane from a light source integral with the screening device;  
during said step of directing light to the membrane, measuring the concentration of light reflected from the membrane by a photosensitive detector integral with the screening device, wherein said photosensitive detector generates output signals representative of the concentrations of light reflected by the membrane test zone and control zone;  
with a processor integral with the screening device, based on the output signals from the photosensitive detector, compare the concentration of light reflected by the control zone to a first reference value to determine if the test is successful;  
with the processor, based on the output signals from the photosensitive detector, compare the concentration of light reflected by the test zone to a second reference value; and  
if said comparison of the concentration of light reflected by the control zone to a first reference value indicates the test was successful, with the processor, based on said comparison the concentration of light reflected by the test zone to the second reference value, generating data representative of the presence/absence of the compound in the specimen.

C4

43. (New) The method of performing a screening test of Claim 42, wherein:

the membrane background zone reflects a fixed amount of light;

during said step of measuring the concentration of light reflected by the membrane, the photosensitive detector further generates output signals representative of the concentrations of light reflected by the background zone; and

in said comparison of the concentration of light reflected by the control zone to the first reference value, the processor compares the concentration of light reflected by the control zone to the concentration of light reflected by the background zone.

44. (New) The method of performing a screening test of Claim 42, wherein:

the membrane background zone reflects a fixed amount of light;

during said step of measuring the concentration of light reflected by the membrane, the photosensitive detector further generates output signals representative of the concentration of light reflected by the background zone; and

in said comparison of the concentration of light reflected by the membrane test zone to the second reference value, the processor compares the concentration of light reflected by the test zone to the concentration of light reflected by the background zone.

C4 45. (New) The method of performing a screening test of Claim 42, wherein, in said comparison of the concentration of light reflected by the test zone to the second reference value, the processor compares the concentration of light reflected by the test zone to the concentration of light emitted by the control zone.

46. (New) The method of performing a screening test of Claim 42, wherein:

as a consequence of said step of directing light to the membrane, the light reflected by the test zone and the control zone is visible light; and

in said step of measuring the concentration of light reflected from the membrane, the concentrations of visible

light reflected by the test zone and the control zone are measured.

47. (New) The method of performing a screening test of Claim 42, wherein, if said comparison of the concentration of light reflected by the control zone to a first reference value indicates the test was successful, the processor, based on said comparison of the concentration of light reflected by the test zone to the second reference value, generates data representative of a qualitative analysis of the presence of the compound in the specimen.

48. (New) The method of performing a screening test of Claim 42, wherein, if said comparison of the concentration of light reflected by the control zone to the first reference value indicates the test was successful, the processor, based on said comparison of the concentration of light reflected by the test zone to the second reference value, generates data representative of a quantitative analysis of the presence of the compound in the specimen.

C4 49. (New) The method of performing a screening test of Claim 42, wherein:

if said comparison of the concentration of light reflected by the control zone to a first reference value indicates the test was not successful, generating on a display a message indicating the test was not successful; and

if said comparison of the concentration of light reflected by the control zone to a first reference value indicates the test was successful, based on said comparison of the concentration of light reflected by the test zone to the second reference value, generating a message on the display indicating the presence/absence of the compound in the specimen.



50. (New) The method of performing a screening test of Claim 42, wherein:

in said step of measuring the concentration of light reflected from the membrane, the photosensitive detector assembly generates output signals representative of concentration of light reflected from the membrane across the test zone, the control zone and background zones that border the test zone and the control zone; and

with the processor,

based on the output signals representative of the concentration of light reflected by the test zone and background zones on opposed sides of the test zone, determining the concentration of light reflected by the test zone; and

based on the output signals representative of the concentration of light emitted by the control zone and background zones on opposed sides of the control zone, determining the concentration of light reflected by the control zone.

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51. (New) The method of performing a screening assay of Claim 42, wherein, prior to the specimen being flowed over the membrane, the specimen is mixed with label present in said cartridge so that a mixture of the specimen and the label are flowed over the membrane test zone and the membrane control zone and the test zone is formed of material that changes reflectivity as a function of the compound in the specimen-label mixture.

52. (New) The method of performing a screening assay of Claim 42, further including the steps of:

with the processor, based on the measured concentration of light reflected from the membrane, determining the position of the control zone on the membrane;

with the processor, based on the position of the control zone on the membrane, determining the position of the test zone on the membrane;

with the processor, based on the output signals from the photosensitive detector and the position of the test zone on the membrane, determining the concentration of light reflected from the test zone.

53. (New) A screening assembly for testing for the presence of a compound in a specimen, said assembly including:

a cartridge having:

a housing, said housing having a window; and *not in I*

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a membrane mounted to said housing having a portion that is exposed through the housing window, the exposed portion of said membrane having at least one test zone that changes reflectivity as a function of the concentration of the compound in the specimen, at least one control zone that changes reflectivity upon the application of the specimen and a background zone, wherein

said housing is formed with an opening separate from the window through which the specimen is introduced into said housing for application to said membrane; and a screening device, said screening device having:

a receiving bracket for removably holding said cartridge;

a light source directed to the housing window of said cartridge for illuminating the exposed portion of said membrane;

a photosensitive detector directed to said cartridge for receiving light reflected by the exposed portion of

said membrane, said photosensitive detector generating output signals representative of the concentration of light reflected by the zones on said membrane;

a processor connected to said photosensitive detector to receive the photosensitive detector output signals and configured to, based on the output signals:

compare the concentration of light reflected from the membrane control zone to a first reference value to determine if the test is successful;

compare the concentration of light reflected from the membrane test zone to a second reference value; and

if the test is successful, generate data representative of the presence of the compound in the specimen based on the comparison of the concentration of light reflected from the membrane test zone to the second reference value.

Cf 54. (New) The screening assembly of Claim 53, wherein said screening device processor is further configured to determine the second reference value based on the concentration of light reflected from the membrane control zone.

55. (New) The screening assembly of Claim 53, wherein said screening device processor is further configured to:

based on the output signals from said photosensitive detector, determine the position of the control zone on said membrane;

based on the determination of the position of the control zone on said membrane, determine the position of the test zone on said membrane; and

based on the position of the test zone on said membrane and the photosensitive detector output signals, determine the concentration of light reflected from the test zone.

56. (New) The screening assembly of Claim 55, wherein: said screening device photosensitive detector generates output signals representative of concentration of light reflected from the exposed portion of said membrane across the test zone, the control zone and background zones that border the test zone and the control zone; and

said screening device processor is further configured to: based on the output signals representative of the concentration of light reflected by the test zone and background zones on opposed sides of the test zone, determine the concentrations of light reflected by the test zone; and, based on the output signals representative of the concentrations of light reflected by the control zone and background zones on opposed sides of the control zone, determine the concentration of light reflected by the control zone.

C4 57. (New) The screening assembly of Claim 53, wherein said screening device further includes a mirror for reflecting light from the exposed portion of said membrane to said photosensitive detector.

58. (New) The screening assembly of Claim 53, wherein said screening device further includes a battery for energizing said light source, said photosensitive detector and said processor.

59. (New) The screening assembly of Claim 53, wherein said screening device light source includes at least one LED.

60. (New) The screening assembly of Claim 53, wherein said screening device photosensitive detector is a charge coupled device.

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61. (New) The screening assembly of Claim 53, wherein said screening device processor is further configured to, if the test is successful, based on the comparison of the concentration of light reflected from the test zone to the second reference value, generate data representative of a qualitative analysis of the presence of the compound in the specimen.

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